# Product Information

## Freevent Dressing Foam

**Product description:**

The Freevent Dressing Foam 65x70 is a single use foam dressing that provides a protection between the tracheostomy tube and the skin and absorb secretions. It is intended for patients with small secretion.


Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

# Product Information

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| **Document ID:** | PF093-01-TechInfo | **Edition:** | 3.0 |

**Manufacturer:**
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

**Classification: (EU) 2017/745** Class I, Rule 1

**Intended Use:** Freevent Dressing Foams are single use tracheostomy dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

**Use specifications:**

**Intended medical indication**
Patients using a tracheostomy tube.

**Intended patient population**
Adult and pediatric patients using a tracheostomy tube. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

**Intended usage**
Single use.

**Intended part of the body/type of tissue applied to or interacted with**
Skin around tracheostoma.

**Intended user profile**
Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

**Intended conditions of use**
FreeVent Dressings are for single use and for daily continuous use. Intended for use at home (indoor and outdoor), care facilities and hospitals, during rest, sleep and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc. Freevent Dressing Foam should be exchanged when needed, or at least every 24 hours.

**Operating principles**
The FreeVent Dressing Foam is to be placed between the tracheal cannula and the skin.
For hygienic reasons, the FreeVent Dressing Foam should be exchanged when needed/saturated (indicated by increase in size of the dressing foam), at least with every cannula change, or every 24 hours.
The FreeVent Dressing Foam can either be used alone or in combination with other tracheostomy dressings.

**Contraindications:** None

**CE Mark:** Yes. Devices are CE-marked.

**GMDN code:** 15624 (Tracheostomy tube dressing)

**Sterilization:** Non-sterile

# Product Information

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| **Raw material:** | Polyurethane foam |
| **Latex information:** | Not manufactured with natural rubber latex |
| **Biological origin:** | The device is not manufactured with materials derived from human or animal source. |
| **Handling and storage:** | Store the product dry and away from sunlight at room temperature. Excursions permitted between 2 °C – 42 °C. |
| **Waste handling and disposal:** | Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard. |
| **Hazardous components:** | None |
| **Expiration date:** | 5 years after manufacturing. |
| **Packaging:** | 10 products are packed in a Mini-grip plastic bag made of polyethylene together with instructions for use. |

# Product Information

**Devices under Basic UDI-DI: 7331791-COM-0-000-0004-5B**

| REF | Name | UDI-DI |
|---|---|---|
| 1431 | Freevent Dressing Foam 65x70 | 07331791006784 |

**Atos Medical AB compatible products:**

None

Document Approvals

Approved Date: 2024-11-04

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| Task: Approval Task<br>Verdict: Approve | HUABOD Adrienn Bodonyi, Product Support Specialist<br>(huabod@coloplast.com)<br>Issuer<br>24-Sep-2024 09:18:42 GMT+0000 |

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|---|---|
| Task: Approval Task<br>Verdict: Approve | ADEL.KHWATMI Adel Khwatmi, Sustaining Engineer<br>(adel.khwatmi-atosmedical@coloplast.com)<br>Technical / Specialist<br>03-Nov-2024 16:19:19 GMT+0000 |

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|---|---|
| Task: Final Approval<br>Verdict: Approve | KARNIL Karolina Nilsson, Head of Regulatory Affairs<br>(karolina.nilsson-atosmedical@coloplast.com)<br>Regulatory<br>04-Nov-2024 20:52:01 GMT+0000 |